April 28, 2023

T.A.G. Medical Products Corporation, Ltd
Shlomi Dines
RA/QA Director
T.A.G. Medical Products Corporation, Ltd
Gaaton, 2513000
Israel

Re: K230058
Trade/Device Name: Bladeless Trocar - Artemis Lap Cannula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 29, 2023
Received: March 29, 2023

Dear Shlomi Dines:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.04.28 14:38:20 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230058

Device Name
Bladeless Trocar – Artemis Lap Cannula

Indications for Use *(Describe)*
The Artemis Lap Cannula has applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for minimally invasive instruments. Artemis Lap Cannula may be used for primary and secondary insertions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Prepared on: 2023-04-27

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

Contact Details

Applicant Name:	T.A.G. Medical Products Corporation, Ltd.
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Applicant Contact:	Shlomi Dines
Applicant Contact Email:	sdines@tag-med.com

Device Name

Device Trade Name:	Bladeless Trocar – Artemis Lap Cannula
Common Name:	Endoscope and accessories
Classification Name:	Endoscope and accessories
Regulation Number:	876.1500
Product Code:	GCJ

Legally Marketed Predicate Devices

Predicate #:	K032676
Predicate Trade Name:	ENDOPATH III Trocar System
Product Code:	GCJ

Device Description

Artemis Lap Cannula system is a radiolucent, reusable, bladeless laparoscopic trocar, consisting of a cannula, an obturator, a depth limiter, and a disposable standalone seal pack. The trocar is available in two diameters: Ø5mm and Ø12mm, each consists of 4 different length variants. Depth limiter component is available in two diameters and fits either the Ø5mm or Ø12mm cannula regardless of the length. Depth limiter can be used to prevent over penetration during surgical procedures. Artemis Lap Cannula may be used in abdominal, thoracic, or gynecological procedures.

Indications for Use

The Artemis Lap Cannula has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for minimally invasive instruments. Artemis Lap Cannula may be used for primary and secondary insertions.

Comparison of Technological Characteristics

The proposed device and the predicate device (K032676) have the same basic design, intended use, and sterilization. In comparison to the predicate device, the proposed modifications include differences in the sleeve and obturator material, packaging configuration, sleeve design, and the inclusion of a depth limiter. Differences between the proposed and predicate device do not raise new questions of safety or effectiveness.

Comparison to Predicate			
Device	**Subject Device**	**Predicate Device**	**Comparison**
Device Description Summary	Artemis Lap Cannula system is a radiolucent, reusable, bladeless laparoscopic trocar, consisting of a cannula, an obturator, a depth limiter, and a disposable standalone seal pack. The trocar is available in two diameters: Ø5mm and Ø12mm, each consists of 4 different length variants. Depth limiter component is available in two diameters and fits either the Ø5mm or Ø12mm cannula regardless of the length. Depth limiter can be used to prevent over penetration during surgical procedures. Artemis Lap Cannula may be used in abdominal, thoracic, or gynecological procedures.	The ENDOPATH III Trocars are sterile single patient use instruments consisting of a radiolucent sleeve and obturator in sizes ranging from 5-12 mm in diameter. There are three different obturators Bladeless, Blunt Tip and Dilating Tip. The Bladeless obturator contains a clear, tapered optical element, which when used with an endoscope, provides visibility of individual tissue layers during insertion. The Bladeless obturator accommodates an appropriately sized zero endoscope. The Blunt Tip obturator has a blunt plastic tip, which gently moves aside any internal viscera that may be adjacent to the abdominal or thoracic wall. The Dilating Tip obturator has a sharp flat-bladed tip and a spring-loaded shield. The shield on the Dilating Tip obturator is designed to cover the flat-bladed tip to protect internal structures from puncture or	The proposed device and the predicate device have the same basic design, intended use, and sterilization. In comparison to the predicate device, the proposed modifications include differences in the sleeve and obturator material, packaging configuration, sleeve design, and the inclusion of a depth limiter. Differences between the proposed and predicate device do not raise new questions of safety or effectiveness.

		laceration once the abdominal or thoracic cavity has been entered. The trocar sleeve contains two seals, an outer integrated removable self-adjusting seal to accommodate instruments ranging from 5mm to 12mm in diameter where indicated and an internal seal. Together, these seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. The 5mm trocar sleeve does not contain an integrated removable seal and accommodates only 5mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in closed position when it is parallel to the sleeve.	
Indications for Use:	The Artemis Lap Cannula has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for minimally invasive instruments. Artemis Lap Cannula may be used for primary and secondary insertions.	The ENDOPATH III Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions. The ENDOPATH III Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments. The ENDOPATH III Blunt Tip Trocar has applications in	The indications for use are identical to the relevant part if the predicate device cleared under K032676.

		thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments.	
Characteristics/Features:			
Outer Seal Design	Multi-piece (Pacman), overlapping,	Multi-piece (Pacman), overlapping,	Multi-piece (Pacman), overlapping,
Inner Seal Design	Duckbill design	Design Duckbill	Equivalent
Obturator Tip Design	Bladeless	Bladeless	Equivalent
Sleeve Design	Low-profile design	Low-profile design	Equivalent
Obturator Design	Low-profile design	Low-profile design	Equivalent
Cannula Design	Low-profile design	Low-profile design	Equivalent
Outer Seal Material	Polycarbonate and Polyisoprene	Polycarbonate and Polyisoprene	Equivalent
Inner Seal Material	Polyisoprene	Polyisoprene	Equivalent
Dimensions (Diameter)	5 mm & 12 mm	5 mm & 12 mm	Equivalent
Sterilization	Cobalt, irradiation	Cobalt, irradiation	Equivalent
Dimensions (Length)	75 mm, 100 mm, 150 mm	75 mm, 100 mm, 150 mm	Equivelent
Sleeve Material	Radel	Polycarbonate	The proposed device offers the sleeve material in Radel rather than polycarbonate.
Obturator Material	Radel	Polycarbonate	The proposed device offers the obturator material in Radel rather than polycarbonate.
Packaging	Flexible Film Composite, with lidding film top stock (FMP-521®)	Copolyester rigid blister, with heat-sealed Tyvek lid	The proposed device incorporates a different packaging configuration compared to the predicate.
Sleeve Design	Release button for removal and locking of seal pack (includes inner and outer seals)	Release button for removal and locking of outer seal	The proposed device offers a release button for the seal pack of the inner and outer seals whereas the predicate offers a release button for the outer seal only.
Depth Limiter	5 or 12 mm in diameter	Not included with system	The proposed device offers a depth limiter in either 5 or 12 mm in diameter whereas the predicate does not have a depth limiter included in the system.

Nonclinical Testing Discussion

Biocompatibility evaluation was conducted on the proposed device. It was found biocompatible for intended use.

Reprocessing evaluation was conducted on the proposed device. Validated reprocessing instructions are sufficient to clean and sterilize it in healthcare settings.

Nonclinical testing in accordance with ISO 80639-7 was completed. The test data demonstrates success and met the criteria of ISO 80369-7.

Leak testing was conducted on the proposed devices and submitted in this Traditional 510(k). The leak test data demonstrates the proposed devices preform statically equivalent to the predicate device.

Conclusion

Subject and predicate devices have same intended use. Differences in design between the subject and predicate device do not raise new questions of safety or effectiveness. Based on comparison of the technological characteristics, and performance test data, the subject devices is substantially equivalent to the predicate device for requested intended use.